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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,119	03/11/2004	Yih-Lin Chung	55701-004002	8809
69713 7590 07/22/2010 OCCHIUTI ROHLICEK & TSAO, LLP 10 FAWCETT STREET CAMBRIDGE, MA 02138				
EXAMINER HUGHES, ALICIA R				
ART UNIT		PAPER NUMBER		
1614				
NOTIFICATION DATE		DELIVERY MODE		
07/22/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

INFO@ORTPATENT.COM

### Office Action Summary

**Application No.**

10/798,119

**Applicant(s)**

CHUNG, YIH-LIN

**Examiner**

ALICIA R. HUGHES

**Art Unit**

1614

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4 and 6-21 is/are pending in the application.
- 4a) Of the above claim(s) 2-4, 6-10, 12, 13, and 18-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 11, and 14-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 2 sheets.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of the Claims and Examination***

Claims 1-4 and 6-21 are pending currently. However, only claims 1, 11, and 14-17 are the subject of this Office Action, as claims 2-4, 6-10, 12, 13, and 18-21 are withdrawn from consideration, being drawn to a non-elected invention. See 37 C.F.R. 1.142(b).

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 01 July 2010 has been entered.

Applicants' argument, filed on 01 July 2010, has been fully considered and it is deemed to be persuasive regarding the previous rejection. Rejections and objections not reiterated from previous Office Actions are hereby withdrawn.

Upon reconsideration of the pending claims, as presented, the following new rejections are applied. They constitute the complete set of rejections being applied to the instant application presently.

### ***Claim Rejections – 35 U.S.C. §103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 11, and 14-17 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 5,877,213 [hereinafter referred to as “Samid”].<sup>1</sup>

This Office’s arguments from its actions of 23 March 2007, 01 October 2007, 08 April 2008 and 15 April 2009 are incorporated herein by reference in their entirety.

This Office’s previous teachings, as articulated in the office actions of 23 March 2007, 01 October 2007, 08 April 2008, 09 September 2008, 14 April 2009 and 13 May 2010 are incorporated herein by reference.

Applicant now argues that due to the amendment of claim 1 to incorporate the limitation “evaluating the subject for a therapeutic effect of the composition on the skin, mucosa, injured normal tissue or epithelium of the subject,” the claims are not presently met by the prior art.

However, in addition to the previously articulated teachings of Samid, Samid also teaches that sodium phenylacetate and its salt sodium phenylbutyrate have been found to be excellent inhibitors of the growth of specific tumor cells, affecting the proliferation of the malignant cells while sparing normal tissues (Col. 4, lines 40-44). Samid further teaches that “glutamine depletion alone cannot explain the molecular and phenotypic changes observed in vitro following exposure to NaPA. It will be understood, however, that the present invention is not to be limited by any theoretical basis for the *observed results*.” (Col. 4, lines 54-60)(emphasis added). In short, based on the above, there is an evaluation in Samid of the therapeutic effect of the active on the affected area of the subject. Samid also teaches that to “further evaluate the effectiveness of NaPA as an inducer of tumor cell differentiation, the ability of NaPA to induce granulocyte

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<sup>1</sup> Cited on PTO Form 892 filed on 23 March 2007.

differentiation in HL-60 was investigated" ... and that "[t]he direction of differentiation towards granulocytes in cultures treated with NaPA, whether used alone or in combination with RA, was confirmed by microscopic evaluation of cells stained with Wright Stain and the lack of nonspecific esterase activity" (Col. 10, Example 2, lines 20-65). In the same example, Samid teaches the administration of retinoic acid with NaPA (Col. 10, Example 2, lines 20-65). As a result of the foregoing, even the evaluation step of the new limitation in claim 1 is met.

As noted prior, by Applicants' own admission, "the claimed method targets subjects (e.g., cancer patients) who suffer from certain side effects" (Page 9 of Applicants' Remarks). Thus, the patient population in Samid et al and in the instant case may be construed as one in the same. Further, the claims are directed to a "subject in need" and this particular population of need is the population of cancer patients.

In light of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art to administer sodium phenylbutyrate in the manner prescribed by Samid, in combination with radiotherapy, as a method of treating tissue necrosis.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see <http://pair-direct-uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alicia R. Hughes/  
Examiner, Art Unit 1614

/Ardin Marschel/  
Supervisory Patent Examiner, Art Unit 1614